

## **REMARKS**

### **I. INTRODUCTION**

This response is filed in reply to the Office Action mailed December 26, 2007 (the "*Office Action*"). Claims 27, 28, 31-35, 56-59, 61, 62, and 68-77 remain pending. Claims 29, 30 and 64-67 were previously withdrawn. In the Office Action, claims 27, 28, 31-35, 56-59, 61, 62, and 68-77 are rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

### **II. REJECTIONS UNDER 35 U.S.C. §103(a)**

Claims 27-28, 57, 58, 62, 68-72 and 75-77 are rejected under 35 U.S.C. §103(a) as being obvious over the article entitled "*A Combination of Stainless Steel Coil and Compressed Ivalon . . .*," by Zollikofer, et al. ("*Zollikofer et al.*") in view of U.S. Patent 5,258,042 ("*Mehta*"). Although it is not entirely clear from the text of the rejection, it appears that the Examiner is asserting that *Zollikofer et al.* disclose all of the elements recited in these claims with the exception of a hydrophilic polymer comprising a polymeric structure that incorporates an expansion control component such that the hydrophilic polymer expands volumetrically at a controlled rate in an aqueous environment. For this element, the Examiner appears to rely on *Mehta* (*Office Action* at page 2, ¶ 4 through page 3, ¶ 2) from which the Examiner then appears to conclude that the claims of the present application are obvious. The Applicants respectfully disagree.

Section 2141 of the MPEP states:

[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. . . . [T]he analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. . . . Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some

rational underpinning to support the legal conclusion of obviousness.

In the present application, the Applicants' independent claims 27 and 62 recite, in part, a polymeric structure that incorporates an expansion control component such that said hydrophilic polymer expands volumetrically at a controlled rate. Claims 57 and 68 recite, in part, a polymeric structure that incorporates an expansion control component such that said embolizing element, or said hydrophilic polymer, in the case of claim 68, exhibits a delayed volumetric expansion. The Examiner has not clearly articulated how *Mehta* discloses or teaches at least this element of the claimed invention in accordance with the MPEP. In fact, *Mehta* is just as deficient as *Zollikofer et al.* on this issue as is discussed below.

Column 3, lines 5-15 of *Mehta* is the disclosure relied upon by the Examiner to introduce *Mehta* into the rejection but this passage simply describes the common characteristics of a hydrogel, i.e., the characteristics of polymer networks capable of expansion through the absorption of water. Although *Mehta* does disclose that expansion of the hydrogel is essentially completed in "less than 60 minutes, usually 20 to 40 minutes," (Column 6, lines 17-22) it is submitted that one having ordinary skill in the art would recognize that these are simply the observed rates of expansion of a hydrogel *per se*, not of a hydrogel that incorporates into its polymeric structure an expansion control component such that the polymer expands volumetrically at a controlled rate as claimed. In other words, just as with *Zollikofer et al.*, *Mehta* discloses nothing more than a polymeric substance that expands as a result of its inherent water absorption properties.

This is not a trivial deficiency of *Mehta*. For example, in one non-limiting embodiment of the claimed invention the expansion control component is comprised of functional groups of monomers and/or polymers that have either been protonated or deprotonated during the preparation of the hydrophilic polymer. See ¶¶ [0099] and [0100]. When the hydrophilic polymer is hydrated, the expansion thereof is then

governed, e.g., delayed or controlled, by the reverse deprotonation or protonation (as the case may be) of those functional groups See ¶¶ [0106]-[0107]. In other words, the hydrophilic polymer does not expand at the rate otherwise intrinsic to the polymeric formulation (as in *Mehta*). It expands at a controlled rate dictated by the deprotonation or protonation of the functional groups.

One advantage that results from the presence of this control component is that the physician has sufficient time to reposition and even withdraw the device without the need for a restraining agent, encapsulating layer, or non-aqueous carrier fluid. See paragraph [0111]. *Mehta* simply cannot offer this advantage. In the case of *Mehta*, the physician would be beholden to the expansion characteristics intrinsic to the typical hydrogel formulation disclosed in *Mehta*. There is no control component. This gives the physician less margin for safety and thus introduces increased risk to the patient.

As a result, it becomes clear that *Mehta* does not make up for the deficiencies of *Zollikofer et al.* Indeed, it is apparent that *Mehta* is just as deficient as *Zollikofer et al.* on this point. Hence, it is submitted that neither *Zollikofer et al.* nor *Mehta*, either alone or in combination with each other, can be properly relied upon as rendering obvious the claimed invention. Accordingly, withdrawal of the present rejection is respectfully requested.

Claims 31, 32, and 73 and claims 56 and 74 are rejected as being obvious over *Zollikofer et al.* and *Mehta*, as previously discussed, and further in view of U.S. Patent 5,350,397 ("*Palermo et al.*") and U.S. Patent 5,382,259 ("*Phelps et al.*"), respectively. As stated above, *Zollikofer et al.* and *Mehta* fail at least to teach or suggest a polymeric structure that incorporates an expansion control component such that said hydrophilic polymer expands volumetrically at a controlled rate as recited in independent claims 31 and 56. *Palermo et al.* and *Phelps et al.* fail to make up for this deficiency in *Zollikofer et al.* and *Mehta*. Accordingly, the obviousness rejection of these claims similarly fails and Applicants submit that claims 31 and 56, as well as claims 32, 73 and 74, which

depend from claims 31 and 56, respectively, are also allowable. Hence, withdrawal of the present rejection is respectfully requested.

Claims 33-35, 59, and 61, depend from either independent claim 31 or 57. Claims 33-35 are rejected as being obvious over the *Zollikofer et al.*, *Mehta*, and *Palermo et al.* and further in view of U.S. 6,015,424 ("*Rosenbluth et al.*"). Claims 59 and 61 are rejected as being obvious over the *Zollikofer et al.* and *Mehta* and further in view of U.S. 5,695,480 ("*Evans et al.*"). *Rosenbluth et al.*, and *Evans et al.* both fail to make up for the deficiency in *Zollikofer et al.* and *Mehta*, as previously discussed. Accordingly, the obviousness rejection of these claims similarly fails and Applicants submit that claims 33-35, 59, and 61 are also allowable. Hence, withdrawal of the present rejection is respectfully requested.

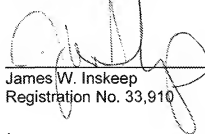
CONCLUSION

In view of the foregoing, it is submitted that pending claims 27, 28, 31-35, 56-59, 61, 62, and 68-77 are in condition for allowance. Hence an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any additional fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,



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